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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,007	DEJEAN ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,18-20 and 28-35* is/are pending in the application.

4a) Of the above claim(s) *1 and 31-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed January 2, 2004.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 34, drawn to a composition of markers, classified in class 536, subclass 23.1.

II. Claims 18-20; 28-30, drawn to tumor suppressor genes, classified in class 536, subclass 23.5.

III. Claims 31-33, drawn to methods for discriminating between HCC with liver cirrhosis and HCC with chronic hepatitis or diagnosing invasive HCC, classified in class 435, subclass 6.

IV. Claim 35, drawn to a method for isolating, purifying or identifying a tumor suppressor gene, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

A) Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the tumor suppressor gene may isolated or purified or identified in materially different methods. For example the tumor suppressor gene may be isolated using a materially different method. Moreover the tumor suppressor gene may be made synthetically.

B) Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the markers of Group I may be used in a materially different method such as isolation, purification of nucleic acids or detection of alternative cancers, for example.

C) The inventions of Group III and IV are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group III is for diagnosing diseases. Alternatively, the method of Group IV is for isolating, purifying or identifying tumor suppressor genes. Therefore the methods are distinct over one another.

D) The inventions of Group I and II are each directed to products. The products of Group I are directed to microsatellite DNA markers, RFLP, VNTR, STS or EST markers. The product of Group II is directed to a tumor suppressor gene. The structure of each of these products differs, as genes encode for a protein. The function of the markers differs from the function of the tumor suppressor gene in that the markers may be used for linkage studies or other analyses.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Ken Meyer on March 5, 2004 a provisional election was made with traverse to prosecute the invention of Group II, claims 18-20, 28-30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 31-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

6. This application claims priority to 09/055,363 filed April 6, 1998 and provisional application 60/043,437, filed April 7, 1997.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specifically, the first line of the specification does not indicate the status of the 09/055,363 application as patented 6,265,161. Appropriate updating is required.

Drawings

7. The drawings are acceptable.

Sequence Rules

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

For example, on page 25, a sequence is presented which does not provide a SEQ ID NO:. No paper or computer copy of the sequence listing is presented in the instant application.

Information Disclosure Statement

9. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

10. The papers filed September 4, 2001 include a cover sheet for an information disclosure statement, however no 1449 or references are provided in the file. Applicant is kindly requested to file or refile each of these items for appropriate consideration by the examiner.

Specification

11. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

12. Claims 19-20, 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 18 and 28 are drawn to tumor suppressor genes. Claims 19-20, 29 are drawn to fragments of the gene. It is clear that Claims to the fragments are broader in scope than the claims to the entire gene, as there is art that may anticipate the fragments which would not read upon the fragments (see rejections below).

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 18-20, 28-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to any tumor suppressor gene which may have been obtained from a YAC clone, amplified and sequenced.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether

the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, Applicant has failed to describe any additional species within the genus of tumor suppressor genes associated with HCC. The specification does not provide any SEQ ID NO: for any tumor suppressor sequence. The specification does not provide any other structure for a tumor suppressor gene. To claim a new tumor suppressor gene adequate structure, formula or physical properties are required and not a mere wish for obtaining the claimed invention. The prior art provides three tumor suppressor genes which are associated with HCC, namely p53, RB and MPL. It is further noted that the claims are not limited to any particular species. Therefore the claims read on not only human, but also mouse, dog, gorilla, insect tumor suppressor genes. Applicant has not disclosed any genomic DNA sequences for additional tumor suppressor genes. Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

With the exception of p53, Rb, and MPL referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of tumor suppressor gene isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid

itself is required. See *Fiers v. Fevel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 18-20, 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tumor suppressor gene of p53, Rb and MPL, does not reasonably provide enablement for any tumor suppressor gene on any chromosome associated with HCC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 18-20, 28-30 are broadly drawn to a tumor suppressor gene associated with HCC. The invention is an class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

The prior art teaches three tumor suppressor genes associated with HCC, namely p53, Rb and MPL.

The prior art also teaches tumor suppressor genes, namely p21, p34, p51, for example which have not been studied with respect to association or involvement in HCC.

Quantity of Experimentation

The quantity of experimentation to practice and make the claimed invention as broadly as claimed in this area is extremely large since there is significant number of parameters which would have to be studied. First, since the claims are drawn to products which are tumor suppressor genes associated with HCC, the claims would require the skilled artisan to isolate and/or identify newly discovered genes. Tumor

suppressor genes already known in the art would not meet the requirements for patentability, as they are drawn to an old product. Therefore, the skilled artisan would be required to research newly identified tumor suppressor genes. The amount of research required to study and identify new tumor suppressor genes is immense. The skilled artisan would also be required to further determine whether the tumor suppressor genes are associated with HCC. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Working Examples

The specification has no working examples of tumor suppressor genes associated with HCC.

Guidance in the Specification.

The specification analyzes several chromosomal regions which demonstrate LOH on certain chromosomes, but there are no teachings of tumor suppressor genes by structure.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art to determine the location and sequence of new tumor suppressor genes and then assay to determine whether the newly discovered tumor suppressor genes are associated with

HCC. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 18-20, 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 18-20 are indefinite over the recitation "the reverse transcribed RNA" because "the reverse transcribed RNA" lacks proper antecedent basis. Regarding claims 18-20, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Finally, it is unclear how the ordinary artisan would perform the steps of the claim such that the sequenced cDNA clones would yield tumor suppressor genes involved in HCC. There are no steps in the method which are specific to finding tumor suppressor genes or tumor suppressor genes associated with HCC.

B) Claims 28-30 are indefinite over the recitation "the reverse transcribed RNA" because "the reverse transcribed RNA" lacks proper antecedent basis in both claims 28

and 30. Further, it is unclear how the ordinary artisan would perform the steps of the claim such that the sequenced cDNA clones would yield tumor suppressor genes involved in HCC. There are no steps in the method which are specific to finding tumor suppressor genes or tumor suppressor genes associated with HCC.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 18-20, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by either Lamb (Mol. and Cell. Biol. Vol. 6, No. 5, pages 1379-1385, May 1986) or Zakut-Houri et al. (Nature, Vol. 306, No. 8, pages 594-597, December 1983) as evidenced by Lee et al (US Pat. 5,635,473, June 1997) or Bressac et al. (Nature, Vol. 350, No. 6317, pages 429-431, 1991).

As provided in MPEP 2113 "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product

itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)."

Lamb teaches the characterization of the human p53 gene (limitations of Claim 18, 28). Lamb teaches that the gene was isolated from genomic and cDNA libraries. The DNA sequence of the human p53 gene and amino acid sequence of the protein is provided (Figure 2). DNA fragments were subcloned into M13 vectors (limitations of Claims 19-20, 29). A restriction enzyme fragment was obtained. Figure 1 provides the human p53 cosmid and organization of the p53 gene. The restriction enzyme sites are indicated. Lamb teaches using plasmid DNAs to be transfected and harvested (page 1380, col. 1)(limitations of Claim 30).

Zakut-Houri et al teaches the cellular tumour antigen p53 (limitations of Claim 18, 28). Figure 1 provides a restriction enzyme map and sequencing strategy of p53 cDNA clones. Zakut-Houri teaches a ZhoI-HaeIII fragment (limitations of Claim 19-20, 29).

Lee teaches that p53 is involved in HCC caused by HBV. Lee teaches that a novel use of p53 as a HBV replication inhibitor which can be developed into an agent for the treatment of acute/chronic hepatitis and prevention of liver cirrohisis and HCC caused by HBV (col. 10, lines 29-33).

Bressac teaches that mutations of the p53 gene found in 50% of primary HCCs from Southern Africa are reported (abstract).

P53 genomic and cDNA were known at the time the invention was made. P53 had been previously associated with HCC. Thus, since Lamb and Zakut-Houri teach every limitation of the instant claim, Lamb and Zakut-Houri anticipate the claimed invention.

17. Claims 18, 20, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Friend et al. (Genbank Accession Number L11910) as evidenced by Fujimoto et al. (Cancer Research, Vol. 54, No. 1, pages 281-285, 1994).

Friend teaches a tumor suppressor gene polynculeotide of the human susceptibility gene. Friend teaches the genomic sequence including introns and exons. Friend teaches the protein sequence. Friend teaches the nucleotides to be joined to form the cDNA.

Fujimoto teaches that loss of the Rb gene was observed in 44% of HCCs from Quidong, China. Thus Rb is associated with and involved in HCC.

Since Friend teaches a nucleic acid which is inherently associated with HCC, Friend teaches all of the limitations of the instant claims.

18. Claims 18-20, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (Life Sciences, Vol. 57, No. 11, pages 1077-1085, 1995).

As provided in MPEP 2113 "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the

product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)."

Wu teaches identifying a human hepatocelular carcinoma associated tumor suppressor gene by differential display PCR. MPL (mitochondria proteolipid like gene) was identified. MPL was analyzed using northern blot analysis which showed 20 of 44% MPL was undetectable in human hepatocelular carcinomas. MPL may be a candidate tumor suppressor gene for human HCC (abstract). After significant analysis, Wu concluded that no large deletion or gross rearrangmeent of the MPL gene was found in HCC. MPL appears to be down regulated in HCC rather than mutated in the tumors (page 1083, para 3). Wu teaches digesting DNA with EcoRI and XhoI restriction enzymes (page 1078)(limitations of Claims 19, 29). Wu teaches reamplified fragments were cloned into the PCRII vector (page 1079)(limitations of Claim 30). Wu also teaches primers and probes for MPL (Figures 2)(limitations of Claim 20).

Wu also teaches that tumor suppressor genes p53 and pRb show changes in expression I nhepatocellular carcinoma (HCC).

Therefore since Wu teaches every limitation of the instant claims, Wu anticipates the claimed invention.

19. Claims 19-20, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796, December 12, 1995).

Brennan teaches oligonucleotides having 10 nucleotides each (10-mers). The oligonucleotides represent every possible permutation of the 10-mer oligonucleotide. Therefore, Brennan teaches every possible 10-mer nucleic acid which are fragments of the tumor suppressor gene obtained by chemical synthesis. The nucleic acids may serve as probes or primers.

Conclusion

20. No claims allowable over the art.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Goldberg

Jeanine Goldberg
Patent Examiner
March 9, 2004